



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dimatteo et al.

Examiner: Uyen T. Ho

Application No.: 10/003,149

Group Art Unit: 3731

Filed: November 2, 2001

Docket: 760-117

For: VAPOR DEPOSITION PROCESS
FOR PRODUCING A STENT-
GRAFT PRODUCED
THEREFROM

Dated: November 3, 2005

Confirmation No.: 7468

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to: Commissioner for Patents, Alexandria, VA 22313

Dated:

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Signature

K. Goodhue, K. J. J. J.

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**DECLARATION OF PRIOR INVENTION IN THE UNITED STATES
TO OVERCOME A CITED PATENT UNDER 37 C.F.R. §1.131**

Sir:

1. We, Kristian DiMatteo, a citizen of the United States, residing at 25 Carleton Road, Waltham, Massachusetts 02451, and Robert C. Thistle, a citizen of the United States, residing at 35 Laurie Lane, Bridgewater, Massachusetts 02324, are the inventors of the above-identified application.

2. At the time of the invention thereof and continuously to the filing of the present application, we were employees of Boston Scientific Corporation which is the parent of SCIMED Life Systems, Inc., assignee of the present application. I, Robert C. Thistle, am

currently an employee of Boston Scientific Corporation. I, Kristian DiMatteo, was an employee of Boston Scientific Corporation until about October 7, 2005. We submit this declaration to establish completion of the invention set forth in this application in the United States at a date prior to September 27, 2000, i.e., the effective date of U.S. Patent No. 6,695,833 to Frantzen (hereinafter "Frantzen") which was cited by the Examiner in an Office Action mailed, September 2, 2005.

3. From the documents submitted herewith and as set forth hereinbelow, it can be seen that the invention set forth in the claims of this application was completed in the United States before September 27, 2000, which is a date earlier than the U.S. filing date of the Frantzen Patent. Such completion being evidenced conception of the invention and reduction to practice of the complete invention with diligence at a date prior to the filing date of the Frantzen reference. Exhibits A through C are submitted in support thereof. The Exhibits A through C are being submitted with their dates redacted. The actual document dates of Exhibits A through C are prior to September 27, 2000. A brief description of the documents being submitted is as follows:

- a. A copy of a Lab Notebook Page (EXHIBIT A), dated prior to September 27, 2000, signed by one of the inventors, i.e., Robert Thistle, evidencing conception of forming a paraylene graft and a paraylene stent-graft. The exhibit further notes that samples were provided to an outside firm to prepare such a stent-graft according to the conception of the present invention detailed therein.
- b. A copy of a Lab Notebook Page (EXHIBIT B), dated prior to September 27, 2000, signed by one of the inventors, i.e., Robert Thistle, recording photographs of one of the five paraylene stent-grafts prepared in accordance with the procedures of EXHIBIT mentioned above.
- c. A copy of a Testing Request (EXHIBIT C), dated prior to September 27, 2000, reporting testing results for the paraylene stent-grafts which were requested by

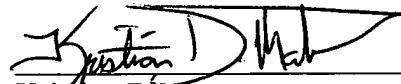
one of the inventors, i.e., Robert Thistle. The testing results include measured thicknesses of the paraylene grafts.

This declaration is being submitted in response to a Final Office Action issued by the Examiner and therefore is believed to be timely filed.

The above-referenced exhibits establish a date of conception of the invention and reduction to practice of the complete invention with diligence at a date prior to September 27, 2000, i.e. the filing date of the Frantzen Patent.

We hereby declare that all statements made herein of my knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 11-27-2005


Kristian DiMatteo

Dated: _____

Robert C. Thistle

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700

one of the inventors, i.e., Robert Thistle. The testing results include measured thicknesses of the parylene grafts.

This declaration is being submitted in response to a Final Office Action issued by the Examiner and therefore is believed to be timely filed.


The above-referenced exhibits establish a date of conception of the invention and reduction to practice of the complete invention with diligence at a date prior to September 27, 2000, i.e. the filing date of the Frantzen Patent.

We hereby declare that all statements made herein of my knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 11-27-2005


Kristian DiMatteo

Dated: February 15, 2006


Robert C. Thistle

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Syosset, New York 11791
(973) 331-1700

Parylene Coating is a clear, medical Grade, polymer film. The Parylene Coating process is one of Vapor Deposition. Due to the sputter process it is ~~finite~~ infinitely controllable relative to thickness.

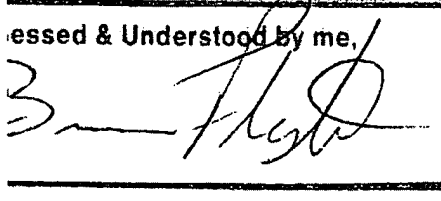
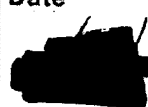
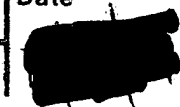


This idea involves the use of Parylene Coating process to form a graft like covering on a Symphysis Stent.

During a plant presentation by Specialty Coatings Systems, the question was asked whether or not the coating could be used to Bridge a Gap or a joint. The example of forming a film over a hole in a washer was given by Kristian Dirckx. Representations of SCS stated the parylene would not create the Bridge.

We have come up with the idea of using the Parylene process to create a Lamination. The process would be to

1. Manufacture a sheet of Parylene on a medium such as GLASS.
 2. Wrap the sheet around another GLASS Rod.
 3. Slide a stent (Symphysis) over the Rod sandwiching the Parylene sheet between the stent and the Rod.
 4. Now Parylene coat the assembly.
- We believe the second depositor process will adhere to the parylene sheet and the OD of the stent, creating a Lamination.

Once the assembly is removed from the Rod the film can be trimmed. Samples were given to Hans Bok for process exploration towards SCS process engineers to review idea and P.O. to be written for samples. Samples Given [REDACTED]

Read & Understood by me, 	Date 	Invented by Thistle / Dirckx	Date 
		Recorded by Robert Thistle	

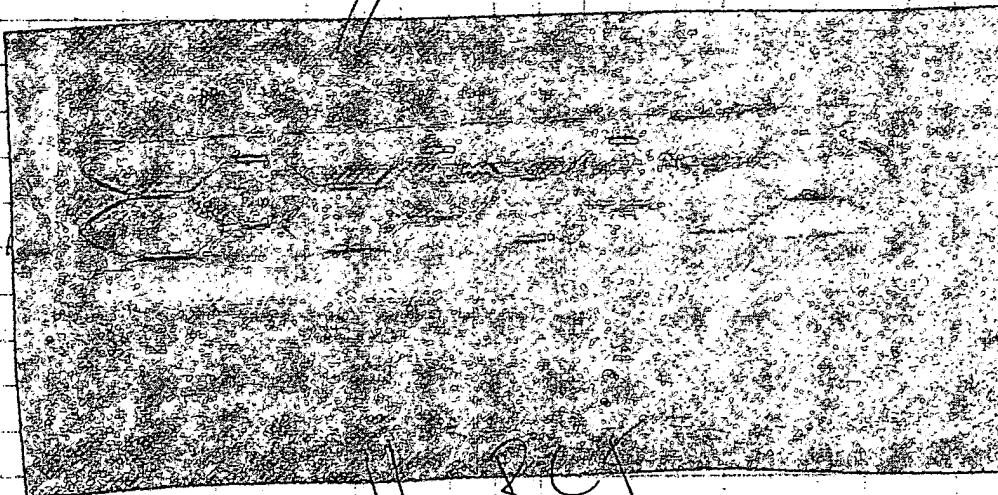
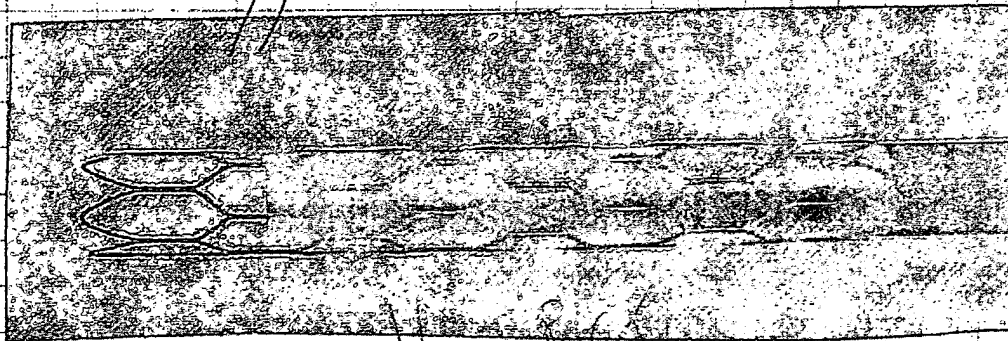
Book No. [REDACTED]

TITLE

Varylene Coating

No. [REDACTED]

Recorded on Page [REDACTED], Book No. [REDACTED]. Samples
Symphony Starts were given to SCS for
BATING. See Page [REDACTED], Book No. [REDACTED] for Returned
Indexing Slip. The following are photos of the returned
pieces. SEM + CROSS sections can be found in Report [REDACTED] (ADVANCED
METALS)



To Page No. [REDACTED]

ed & Understood by me

Date

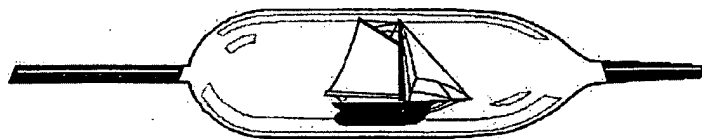
Invented by

Thistle/Dimmer

Date

Recorded by

Bob Thistle



PARYLENE COATED SYMPHONY STENT

TASK NUMBER: [REDACTED]

PREPARED BY:

[REDACTED]
[REDACTED]

R&D METALS - TESTING REQUEST

Part No.:

Description:

Parylene Coated
Symping Stent

Serial No.:

Project No.:

Date:

Requester:

Bob Thsk

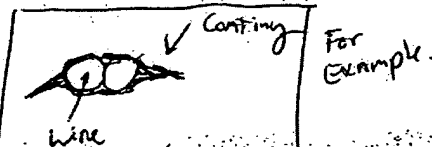
Requested Completion:

Extension:

4545

Special Instructions:

Cross section stent to view profile
of coating.



Testing Requested:

☐ DMA Fatigue []

☐ Stent Weld Shear []

☐ Stent Cell Pull []

☐ Stent Weld Cleave []

☐ NiTi Resistivity []

☐ Wire Tensile []

☐ DSC []

Metallography:

☐ Section & Polish []

☐ Etch []

☐ Photograph []

SEM:

☐ Surface Image & Photo []

☐ EDS Chemical Analysis []

Other: []

☐

Testing Completed By:

Ra Nam

Date:

Comments:

Copies are placed in file
Folder

Report Issued:

Request Number:

[REDACTED]

Description: Parylene Coated Symphony Stent

Project #: [REDACTED]

Requester: B. Thistle

Extension: 4545

Purpose: To examine the profile of coating.

Method: Used Stereo Microscope (Olympus SZH10), Metallography (Buehler Phoenix 4000), and Metallographic Microscope (Olympus BX60) located at Advanced Metals Technology Lab.

Material:

N=1 Parylene coated Symphony Stent

Metallography:

A parylene coated symphony stent was requested for metallographic section to observe the coating profile. Parylene coated symphony stent was sectioned in to five parts. Each part was mounted for cross section. Each part was placed into individual mounting cup and the epoxy with a mixture of 5:1 ratios of resin to hardener was poured into the cup to cover the samples. The samples were left to cure overnight. Samples were removed from the mounting cup and were polished using Buehler Phoenix 4000 machine. 600 and 800 grit were used to remove the materials to the desired location. Nylon cloth, Masertex, and Microcloth were used for a smoother surfaces.

Results:

Metallographic sections showed the parylene coating does embrace the wire uniformly. See attached photos for more information.

[REDACTED]

Cross Section to Parylene Coated Symphony Stent

Mount #	Magnification	Location	Measure Coating Thickness (in)
832	500X	Wires - merge into weld	0.0011 0.0012 0.0011
Average			0.0011

Mount #	Magnification	Location	Measure Crack Length (in)
833	500X	Welds	0.0011 0.0010 0.0010
Average	#DIV/0!		0.0010

Mount #	Magnification	Location	Measure Crack Length (in)
834	500X	Welds	0.0011 0.0011 0.0011
Average	#DIV/0!		0.0011

Mount #	Magnification	Location	Measure Crack Length (in)
835	500X	Wires - Mid section of cell	0.0012 0.0011 0.0016
Average	#DIV/0!		0.0013

Mount #	Magnification	Location	Measure Crack Length (in)
836	500X	Wires - lower part of cell	0.0011 0.0012 0.0011
Average	#DIV/0!		0.0011

Cross Section fo Parylene Coated Symphony Stent

Mount #	Magnification	Location	Measure Coating Thickness (in)
832	500X	Wires - merge into weld	0.0011 0.0012 0.0011
Average			0.0011

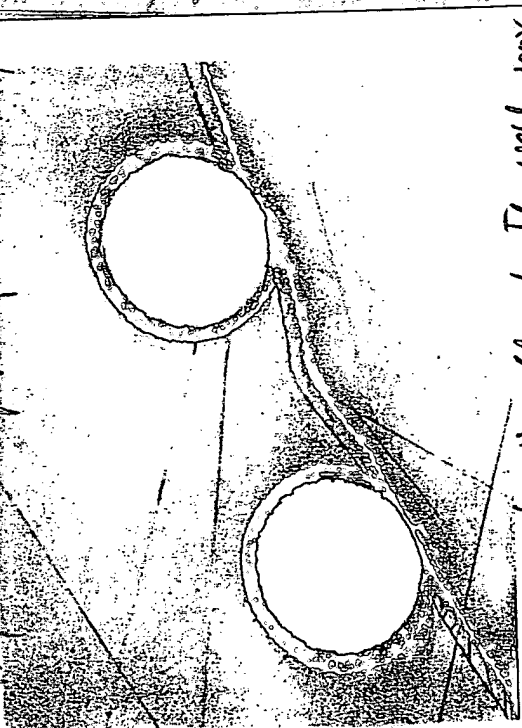
Mount #	Magnification	Location	Measure Crack Length (in)
833	500X	Welds	0.0011 0.0010 0.0010
Average	#DIV/0!		0.0010

Mount #	Magnification	Location	Measure Crack Length (in)
834	500X	Welds	0.0011 0.0011 0.0011
Average	#DIV/0!		0.0011

Mount #	Magnification	Location	Measure Crack Length (in)
835	500X	Wires - Mid section of cell	0.0012 0.0011 0.0016
Average	#DIV/0!		0.0013

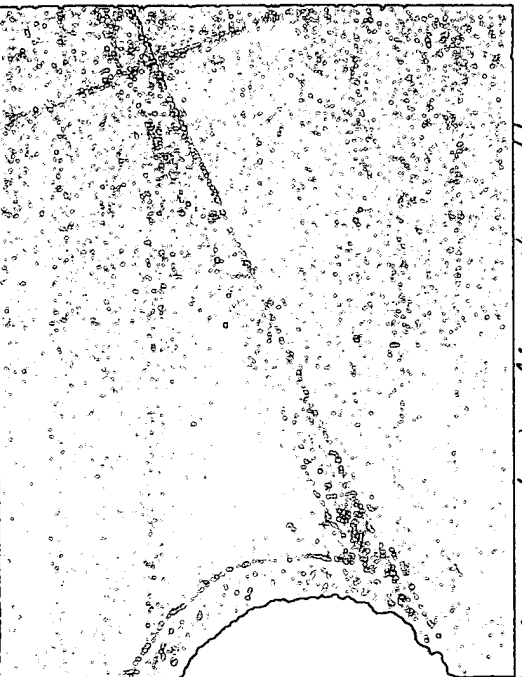
Mount #	Magnification	Location	Measure Crack Length (in)
836	500X	Wires - lower part of cell	0.0011 0.0012 0.0011
Average	#DIV/0!		0.0011

Parylene Coated Symphomy Skirt



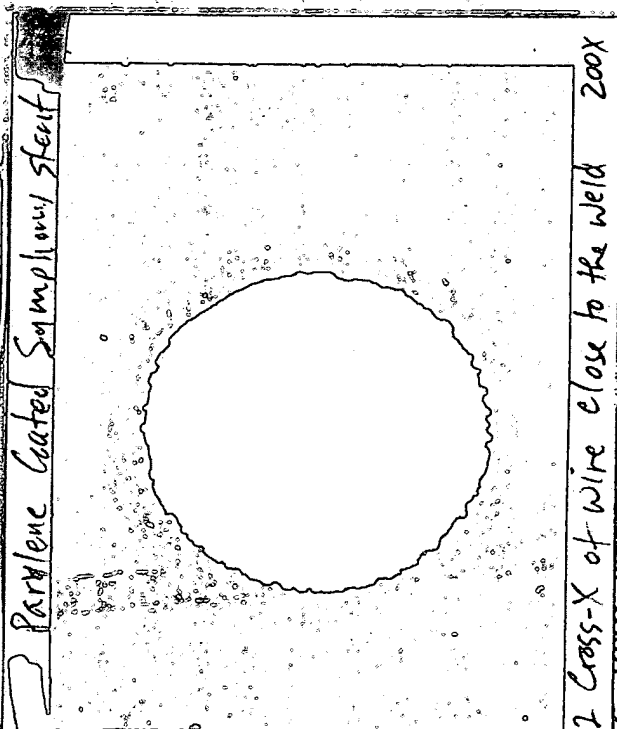
832 Cross-X of wire Close to the Weld 100X

Parylene Coated Symphomy Skirt

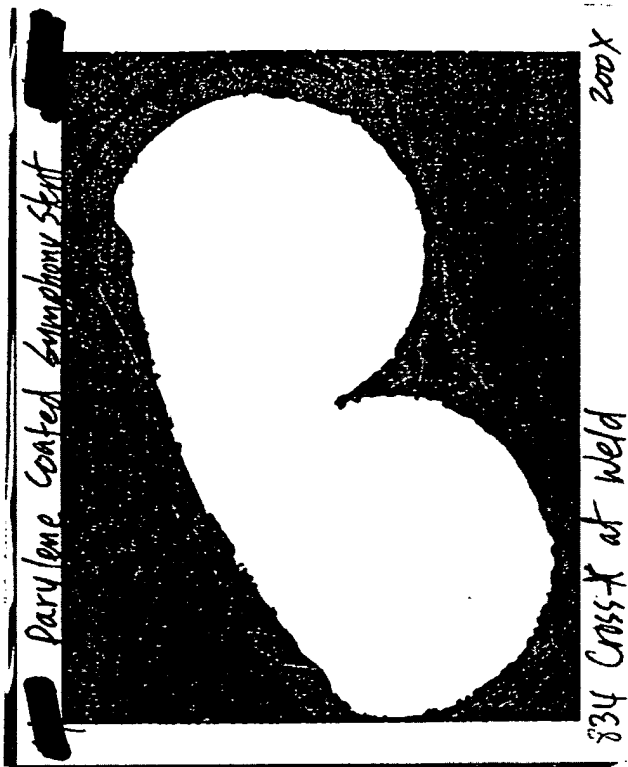
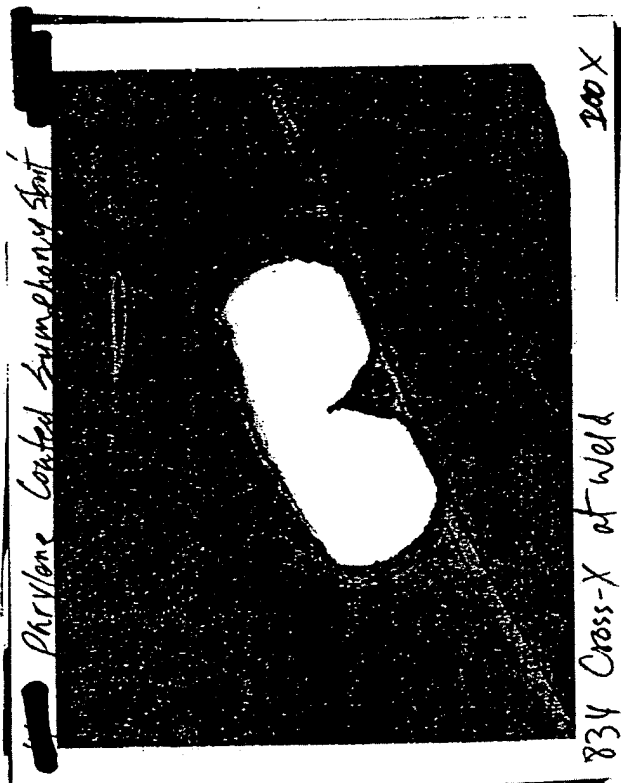
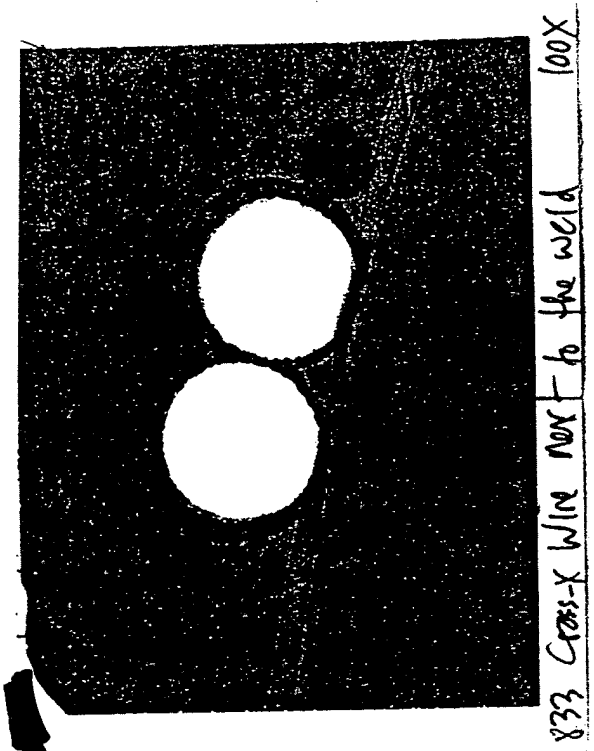
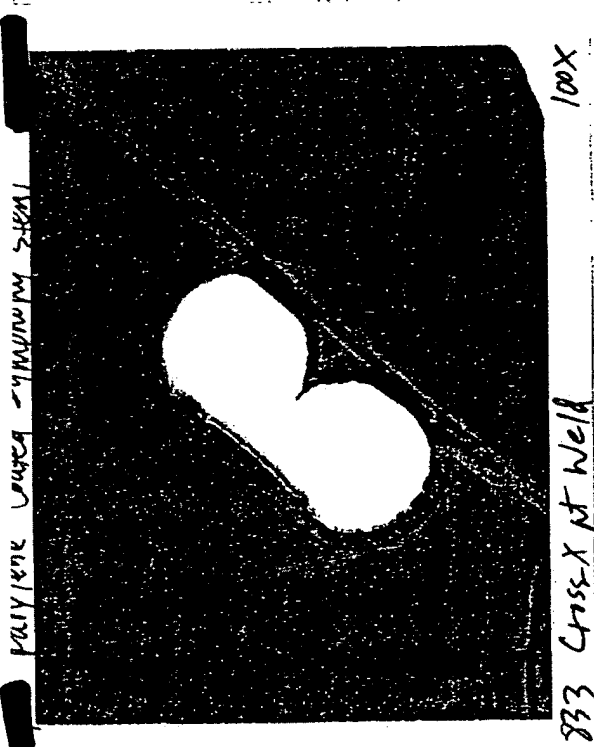


832 Cross-X of wire Close to the Weld 200X

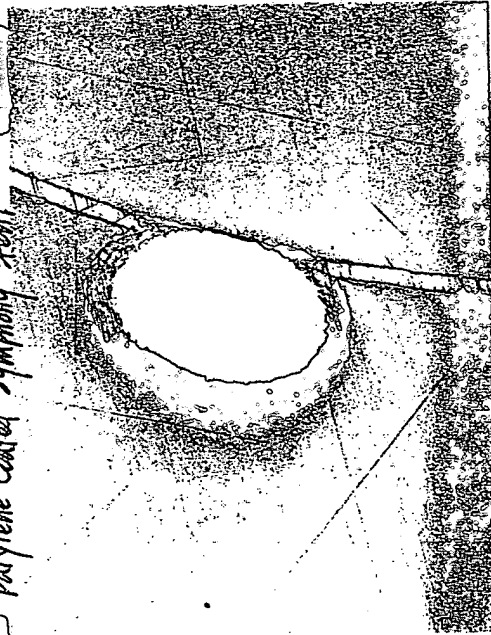
Parylene Coated Symphomy Skirt



832 Cross-X of wire Close to the Weld 200X



Parylene Coated Symphory Stent



835 CROSS-X ON WIRE

100X

Parylene Coated Symphory Stent



835 CROSS-X ON WIRE

200X

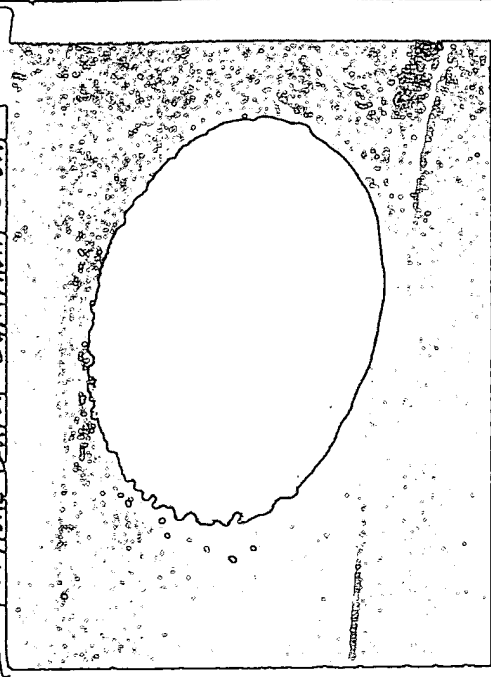
Parylene Coated Symphory Stent



CROSS-X ON WIRE

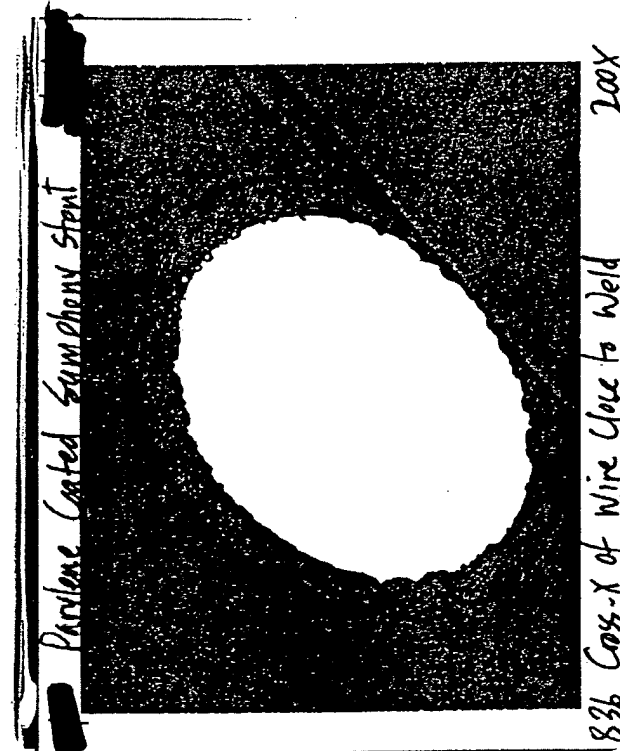
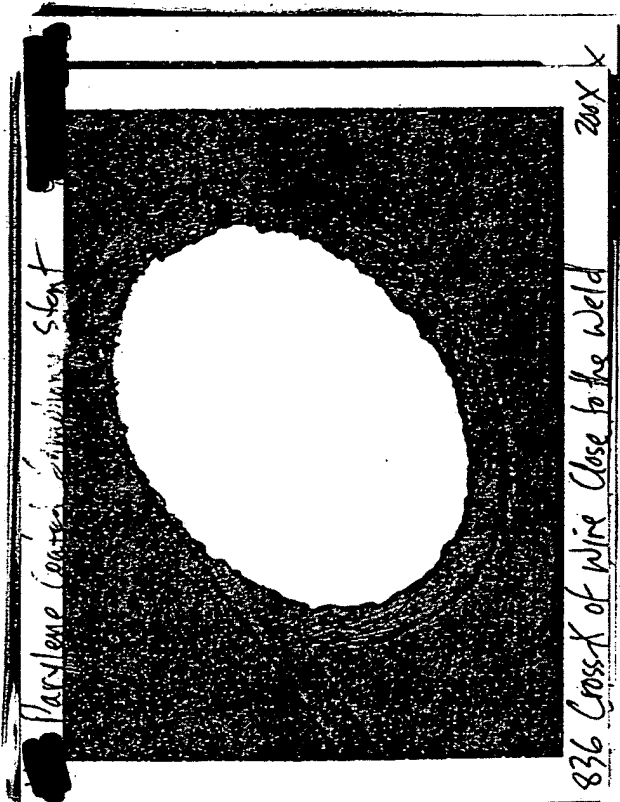
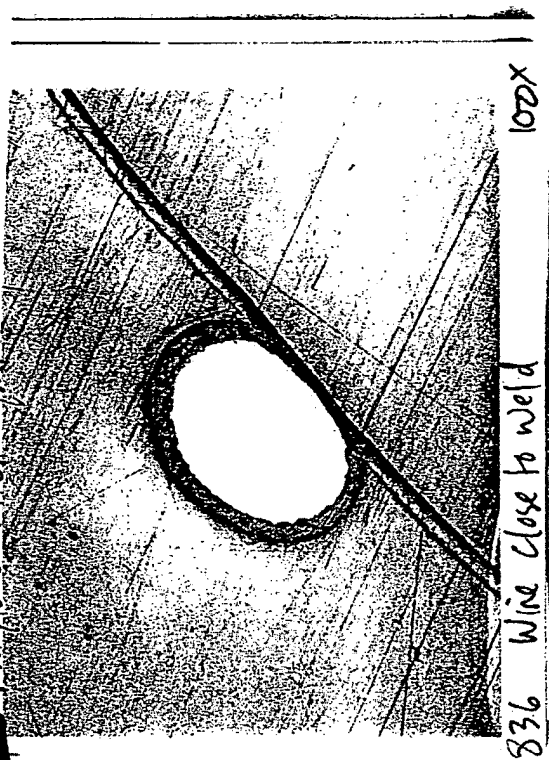
200X

Parylene Coated Symphory Stent



835 CROSS-X ON WIRE

200X



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